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**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION**

This Document Relates To:

Gould, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10444-FDS;
Hannah v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10407-FDS;
Jones v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-cv-10409-FDS;
Leaverton, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10408-FDS;
Letizia, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10442-FDS;
Marko, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10404-FDS;
Normand, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10447-FDS;
Pennington v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10406-FDS;
Ramos v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10410-FDS;
Rios, et. al. v. New England Compounding Pharmacy, Inc., et. al., 13-10411-FDS;
Rivera, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10412-FDS;
Tayvinsky, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10414-FDS;
Tisa, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10446-FDS;
Tolotti, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10413-FDS; and,
Zavacki, et. al. v. New England Compounding Pharmacy, Inc., et. al., Civ. No. 13-10441-FDS

MDL No. 1:13-md-02419

Hon. F. Dennis Saylor, IV

**MOTION OF ALAUNUS
PHARMACEUTICAL, LLC FOR LEAVE
TO FILE REPLY BRIEF IN SUPPORT
OF ITS MOTION TO DISMISS
PURSUANT TO FED.R.CIV. P. 12(b)(6)**

The Defendant, Alaunus Pharmaceutical, LLC (“Alaunus”), by and through its counsel, hereby moves the Court for leave to file the proposed eleven (11) page reply brief, which is attached herewith at Exhibit A, to respond to certain matters raised in *Plaintiffs’ Consolidated Response in Opposition to the Motion to Dismiss of Alaunus Pharmaceutical, LLC*.¹ Specifically, Alaunus would like to address the following issues in its reply:

1. The Plaintiffs’ contention that the pleading standards from the state of New Jersey apply in connection with Alaunus’ 12(b)(6) motion, rather than the federal pleading standards articulated by the Supreme Court in *Twombly* and *Iqbal*;
2. The Plaintiffs’ attempt through their Consolidated Response to cure the deficient factual allegations in their complaints with new allegations and references to websites and other documents that were not asserted in, referenced, or annexed to their complaints; and,
3. The merits of Plaintiffs’ contention that their complaints raise a plausible inference that Alaunus was directly involved in the manufacture, sale, and distribution of methylprednisolone acetate (“MPA”) by virtue of the common ownership of Alaunus and New England Compounding Pharmacy Inc. (“NECC”), and the adjacent location of their principal places of business.

Alaunus should be granted leave to file the attached reply brief for many reasons.

The complaints that are the target of this Motion to Dismiss were brought by fifteen (15) plaintiffs² against the same three companies, NECC, Alaunus, Ameridose, LLC, as well as multiple healthcare providers, specifically Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, also trading as Premier Orthopaedic Associates (“Premier Orthopaedics”), Premier Orthopaedic Associates Surgical Center, LLC (“Surgical Center”), South Jersey Healthcare (“SJH”), South Jersey Regional Medical Center (“SJRMC”), Professional Pain Management Associates (“Professional Pain”), Kimberley Yvette Smith, M.D.,

¹ Plaintiffs did not file their Consolidated Response in the Master Docket. Plaintiffs did file their Consolidated Response in each of the individual dockets listed in the caption of this Motion.

² The fifteen (15) plaintiffs subject to Alaunus’ Consolidated Motion to Dismiss include those identified in the caption of this Motion.

a/k/a Kimberley Yvette Smith-Martin, M.D. ("Dr. Smith"),³ Vannette Perkins, M.D. ("Dr. Perkins"), Nitesh Bhagat, M.D. ("Dr. Bhagat"), John Doe(s) Corporations (1-4), and John Doe(s) M.D. (1-3) (collectively referred to as the "Healthcare Provider Defendants"). All fifteen of these plaintiffs make virtually identical injury allegations, specifically that each plaintiff suffered injuries as a result of exposure to an allegedly contaminated steroid product, methylprednisolone acetate ("MPA"), compounded by NECC. Similarly, all of these plaintiffs assert identical causes of action couched in liability under the New Jersey Product Liability Act ("NJPLA"), negligence, breach of express warranty, and loss of consortium.⁴ Moreover, all of these plaintiffs reside in New Jersey, were allegedly administered the MPA product in New Jersey, and in fact are all represented by the same counsel.⁵

The MPA product, around which this litigation revolves, is an injectable steroid often used for pain management, is only available to licensed healthcare providers, and was compounded and distributed by NECC in Framingham, Massachusetts. On September 26, 2012, NECC initiated a nationwide recall of the MPA product after the Food and Drug Administration ("FDA") and the U.S. Centers for Disease Control and Prevention ("CDC") investigated multiple state reports of fungal meningitis among patients whom received an epidural steroid injection from one of three lots of MPA compounded in 2012 at NECC. NECC voluntarily ceased operations, surrendered its license to the Massachusetts Board of Registration in Pharmacy on October 3, 2012, and subsequently initiated a voluntary recall of all its products. On December 21, 2012, NECC filed for bankruptcy. Alunus filed its Consolidated Motion to Dismiss on

³ All plaintiffs name Dr. Smith as a defendant except for Ramos and Rivera, whom name Dr. Bhagat as a defendant, and Plaintiff Pennington whom names Dr. Perkins as a defendant.

⁴ Only Plaintiffs Hannah, Jones, Pennington, and Ramos do not make claims for loss of consortium.

⁵ Various plaintiffs subject to this Motion to Dismiss have filed amended complaints, while others have not. For simplicity sake, this memorandum will refer to the original complaints and the amended complaints that were filed by the fifteen (15) plaintiffs simply as the "Complaint."

February 22, 2013. No objection having been filed by the New Jersey Plaintiffs to the Judicial Panel on Multidistrict Litigation's Conditional Transfer Order # 1, all fifteen of the cases filed by the New Jersey Plaintiffs were transferred to this Court and consolidated with the other related actions in this multi-district litigation on February 28, 2013. The New Jersey Plaintiffs filed their Consolidated Response to Alaunus' Motion to Dismiss on March 6, 2013.

In Alaunus' Consolidated Motion to Dismiss the complaints filed by the New Jersey Plaintiffs, Alaunus argued that Plaintiffs do not plead sufficient facts to show that Alaunus is vicariously liable for NECC's alleged tortious conduct under an alter-ego liability theory. Plaintiffs' basis for Alaunus' liability is based solely on conclusory assertions, with no factual support. Each Complaint impermissibly "lumps" NECC, Ameridose, and Alaunus together for the purpose of misleading this Court into believing they are the same company, when in reality each are separate and distinct entities. Plaintiffs' claims under the NJPLA must fail because they do not show that Alaunus is a "manufacturer" or "seller" of the MPA product as defined under the NJPLA, or had any involvement whatsoever in that products' compounding, distribution, or marketing. Under New Jersey law, claims for negligence and loss of consortium are subsumed under the NJPLA, and may not be sustained as separate actions against an alleged "manufacturer" or "seller." Finally, Plaintiffs fail to identify any express warranty made in connection with the MPA product made by Alaunus.

In addition to the complexity of this matter, Plaintiffs raised numerous issues in their Opposition Memorandum which were not and could not reasonably have been addressed in Alaunus' original memorandum in support of its Motion to Dismiss. The New Jersey Plaintiffs contend, among other things, *incorrectly* that the pleading standards from the state of New Jersey apply in connection with Alaunus' 12(b)(6) motion, rather than the federal pleading standards articulated by the Supreme Court in *Twombly* and *Iqbal*. The Plaintiffs' also improperly attempt

through their Consolidated Response to cure the deficient factual allegations in their complaints with new allegations and references to websites and other documents that were not asserted in, referenced, or annexed to their complaints. Moreover, the Plaintiffs' contend, without any legal support, that their complaints raise a plausible inference that Alaunus was directly involved in the manufacture, sale, and distribution of MA by virtue of the common ownership of Alaunus and NECC, and the adjacent location of their principal places of business.

A reply brief on these issues will aid this Court in its decision on Alaunus' Motion to Dismiss. For these reasons, Alaunus respectfully requests that this Court allow this Motion for Leave to File the Proposed Consolidated Reply Brief In Support Of Alaunus Pharmaceutical, LLC's Motion To Dismiss Pursuant To Fed.R.Civ. P. 12(B)(6), which is attached as Exhibit A to this Motion.

Dated: March 11, 2013

Respectfully submitted,
Defendant Alaunus Pharmaceutical, LLC
By its Attorneys,

/s/ Ryan Ciporkin

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CERTIFICATE OF SERVICE

I, Ryan Ciporkin, hereby certify that the documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: March 11, 2013

/s/ Ryan Ciporkin

Ryan Ciporkin